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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/865,022	05/24/2001	Robert P. Hebbel	600.449US1	3307

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12/02/2002

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EXAMINER

NGUYEN, QUANG

ART UNIT

PAPER NUMBER

1636

DATE MAILED: 12/02/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/865,022

Applicant(s)

HEBBEL ET AL

Examiner

Quang Nguyen, Ph.D.

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 September 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-46 is/are pending in the application.
- 4a) Of the above claim(s) 15-43 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-14, 45 and 46 is/are allowed.
- 6) ☒ Claim(s) 44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Applicants' amendment filed on 9/11/2002 in Paper No. 10 has been entered.

Claims 1-45 and newly added claims 45-46 are pending in the present application.

This application contains claims 15-43 drawn to an invention nonelected with traverse in Paper No. 8. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claims 1-14 and 44-46 are examined on the merits herein.

The text of those sections of Title 35 U.S.C. Code not included in this action can be found in a prior Office Action.

Response to Amendment

The 35 U.S.C. 103 rejections as being unpatentable over Drau et al. (U.S. 6,352,555) in view of various references are withdrawn.

Priority

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)).

Claim R ejections - 35 USC § 102

Claim 44 remains rejected under 35 U.S.C. 102(b) as being anticipated by Asahara et al. (Science 275:964-967, 1997) or Levine et al. (U.S. Patent No. 5,132,223) for the reasons already set forth in the previous Office Action.

Asahara et al. teach a proliferated spindle shaped endothelial cell culture population with surface cell markers CD34, CD31, flk-1, Tie-2, E selectin among others prepared from CD34-positive mononuclear blood cells freshly isolated from human peripheral blood (see abstract and page 965, col.1-col. 2). Levine et al. disclose expanded endothelial cell populations derived from human umbilical vein and adult human blood vessels (see Brief summary of the invention). It is noted that the claim is a product by process claim, and since the proliferated endothelial cell population of Asahara et al. or that of Levine et al. is indistinguishable from a population of expanded endothelial cells prepared by the method of the instant invention, Asahara et al. and Levine et al. anticipate the instant claim.

Response to Arguments

Applicants' arguments related to the above rejection in the Amendment filed on 9/11/2002 in Paper No. 10 (pages 3-4) have been fully considered.

With respect to the Asahara reference, Applicants argue that the cells in the expanded endothelial cell population of the presently claimed invention have the typical "cobblestone" morphology of endothelial cells, whereas the cells obtained by Asahara et al. are spindle shaped, and therefore the Asahara reference can not anticipate the claim. Applicants' argument is respectfully found to be unpersuasive because the

distinguishing feature between the cells in the expanded endothelial cell population of the presently claimed invention and the endothelial cells of Asahara is not recited in the claim.

With respect to the Levine patent, Applicants argue that Factor-VIII-related antigen that is used to characterize the endothelial cells of Levine is not an endothelial cell-specific marker, and that Levine et al. do not provide evidence that the cultured cells include an expanded population of endothelial cells (endothelial cells which have multiplied). Therefore, Levine patent does not anticipate the instant claim. Applicants' arguments are respectfully found to be unpersuasive because although Factor-VIII-related antigen may not be an endothelial specific marker, the cultured cells of Levine are endothelial cells (see the entire patent and the claims), and that these endothelial cells have vigorous growth with cell population doubling times of 13-21 hours for 60 to 85 populations doublings. This means that the endothelial cell culture of Levine et al. contains expanded endothelial cells that have multiplied or proliferated (see abstract and claims).

Accordingly, claim 44 remains rejected for the reasons set forth above.

Conclusions

Claims 1-14 and 45-46 are allowed.

At the effective filing date of the present application, the prior art does not teach or reasonably suggest a process for expanding a population of endothelial cells obtained from peripheral blood with the recited limitations as claimed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quang Nguyen, Ph.D., whose telephone number is (703) 308-8339.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's mentor, Dave Nguyen, may be reached at (703) 305-2024, or SPE, Irem Yucel, Ph.D., at (703) 305-1998.

Any inquiry of a general nature or relating to the status of this application should be directed to LIE, Tiffany Tabb, whose telephone number is (703) 605-1238.

Quang Nguyen, Ph.D.


DAVE T. NGUYEN
PRIMARY EXAMINER